

telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside a device user facility that are intended for use by a single patient over the life of the device and permanent implants that are tracked devices, after distribution to or implantation in a patient:

(i) The lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside device user facilities that are intended for use by more than one patient and that are tracked devices, after the distribution of the device to the multiple distributor:

(i) The lot model number, batch number, serial number of the device or other identifier necessary to provide for effective tracking of the device;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device;

(v) The location of the device;

(vi) The date the device was provided for use by the patient;

(vii) The name, address, and telephone number of the prescribing physician; and

(viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:

(1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;

(2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and

(3) A quality assurance program that includes an audit procedure to be run for each device product subject to